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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,708	04/06/2001	Henrik Ditzel	1361.005US1	6474

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/828,708	Applicant(s) DITZEL ET AL.	
	Examiner " Neon" Phuong Huynh	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Fax Cover sheet* .

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Claims 1-46 are pending.

Election/Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19 and 33, drawn to an **immunopolypeptide or antibody** and fragment thereof that binds to human gluco-6-phosphate isomerase, an immunopolypeptide encoded in a bacteriophage that is deposited with the ATCC, and a pharmaceutical composition comprising an immunopolypeptide or antibody that binds to human gluco-6-phossphate isomerase, classified in Class 530, subclass 350; Class 424, subclass 184.1.

II. Claims 20-21 and 34 drawn to an **anti-idiotypic antibody** that specifically binds with anti-gluco-6-phosphate isomerase antibody, and a pharmaceutical composition comprising said anti-idiotypic antibody, classified in Class 530, subclass 387.1; Class 424, subclass 131.

III. Claims 22-23 and 35, drawn to a **second immunopolypeptide** that specifically binds with anti-6-phosphate isomerase antibody, and a pharmaceutical composition comprising said second immunopolypeptide, classified in Class 530, subclass 350.

IV. Claims 24-26, 36 and 46, drawn to an **antisense oligonucleotide** that specifically hybridizes with a polynucleotide encoding anti-glucose-6-phosphate isomerase antibody, and a pharmaceutical composition comprising said antisense oligonucleotide, classified in Class 536, subclass 24.5.

V. Claims 27-28, and 37 drawn to a **conjugate** of human glucose-6-phosphate isomerase covalently bonded to a cytotoxic agent, and a pharmaceutical composition comprising said conjugate, classified in Class 424, subclass 193.1 and 185.1.

VI. Claims 29-32, drawn to a **nucleotide sequence** encoding an immunopolypeptide or antibody that binds to human gluco-6-phosphate isomerase, classified in Class 536, subclass, and 23.1.

VII. Claim 38, drawn to a **method for diagnosis** of autoimmune disease comprising determining the presence of an immune complex formed by combining the blood sera of a patient with human glucose-6-phosphate isomerase, classified in Class 435, subclass 7.9.

VIII. Claim 39, drawn to a **method for treatment** of a patient having autoimmune disease comprising administering to the patient an effective amount of an immunopolypeptide or **antibody** that binds to human gluco-6-phosphate isomerase, or desensitizing amount of human glucose-6-phophate isomerase, classified in Class 424, subclass 185.1.

IX. Claim 40, drawn to a **method for treatment** of a patient having autoimmune disease comprising administering to the patient an effective amount of a humanized chimeric monoclonal antibody wherein the antibody is an **idiotypic antibody** that specifically binds with anti-glucose-6-phosphate isomerase antibody, classified in Class 424, subclass 131.1.

X. Claim 41, drawn to a **method for treatment** of a patient having autoimmune disease comprising administering to the patient an effective amount of a **second immunopolypeptide** that specifically binds with anti-6-phosphate isomerase antibody, classified in Class 424, subclass 184.1.

XI. Claim 42, drawn to a **method for treatment** of a patient having autoimmune disease comprising administering to the patient an effective amount of **a conjugate** of human glucose-6-phosphate isomerase covalently bonded to a cytotoxic agent, classified in Class 424, subclass 131.1.

XII. Claim 43, drawn to a **method for treatment** of a patient having autoimmune disease comprising administering to the patient an effective amount of an **antisense** oligonucleotide that specifically **hybridizes with a polynucleotide encoding anti-glucose-6-phosphate isomerase antibody**, classified in Class 514, subclass 44.

XIII. Claim 43, drawn to a method for treatment of a patient having autoimmune disease comprising administering to the patient an effective amount of an **antisense** oligonucleotide that **encoding anti-glucose-6-phosphate isomerase**, classified in Class 514, subclass 44.

XIV. Claim 44, drawn to a **method for treatment** of a patient having autoimmune disease comprising filtering the patient's blood extracorporeally through a **filter system** containing immobilized human glucose-6-phosphate isomerase, classified in class 424, subclass 140.1.

XV. Claim 45, drawn to a **method for treatment** of a patient having autoimmune disease comprising administering to the patient an effective desensitizing amount of **human glucose-6-phosphate isomerase**, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products such as polypeptide or antibody, anti-idiotype antibody, polynucleotide, antisense oligonucleotide as claimed differ with respect to structure, physiochemical properties and binding specificity. Therefore, they are patentably distinct.

Inventions of Groups VII-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of diagnosing versus the method of treating using distinct product such as antibody, anti-idiotype antibody, antisense oligonucleotide or polypeptide which differ with their respect to their process steps and endpoints. Therefore, they are patentably distinct.

Inventions of Groups (I-VI) and Groups (VII-XV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product such as polypeptide and antibody as claimed can be used in materially different process such as making antibody or screening assays, respectively. Therefore, they are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.

6. Irrespective of whichever group the applicant may elect, the applicant is further required under 35 U.S.C. 121 to elect:

A) If Group I, II or III is elected, the Applicant is required to elect a specific immunopolypeptide comprising the specific combination of (1) **CDR sequence or triplet of CDR sequences** such as the ones recited in claim 3, (2) **spacer amino acid sequence (framework region sequence)** such as the ones recited in claims 6 and 16, (3) **light variable chain amino acid sequence** such as the ones recited in claims 18 and 19, and (4) **heavy variable chain amino acid sequence** such as the ones recited in claims 18 and 19. These immunopeptide comprising the specific combination of CDR sequence and framework sequence are patentably distinct because the CDR sequences differ with respect to their structures, and binding specificity, the specific framework sequences differ with respect to their structures and when together with the CDR sequence, it provides the structure and the specific functions such as receptor binding, and/or complement lysis of the antibody. Therefore, they are patentably distinct.

B) If Group VI is elected, , the Applicant is required to elect a specific polynucleotide such as the ones recited in claim 30 encoding the specific immunopolypeptide comprising the specific combination of (1) **CDR sequence or triplet of CDR sequences** such as the ones recited in claim 3, (2) **spacer amino acid sequence (framework region sequence)** such as the ones recited in claims 6 and 16, (3) **light variable chain amino acid sequence** such as the ones recited in claims 18 and 19, and (4) **heavy variable chain amino acid sequence** such as the ones recited in claims 18 and 19. These polynucleotide encoding the specific immunopeptide comprising the specific combination of CDR sequence and framework sequence are patentably distinct because the CDR sequences differ with respect to their structures, and binding specificity, the specific framework sequences differ with respect to their structures and when together with the CDR sequence, it

provides the structure and the specific functions such as receptor binding, and/or complement lysis of the antibody. Therefore, they are patentably distinct.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 3, 6, 16, 18 and 19 are generic.

8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

11. Due to the complexity of the claimed invention an oral restriction was not made.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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September 30, 2002

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